Getting a Research Project Approved at the Atlanta VA: Brief Outline and Contact information

Determine if your project meets the definition of VA Research

What is VA Research? VA research is research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have R&D Committee approval.

Determine if you can be a VA Investigator

What is a VA Investigator? A VA investigator is any individual who conducts research approved by the VA R&D committee while acting under a VA appointment on VA time, including full and part-time compensated employees, trainees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970. NOTE: Contractors cannot be VA Investigators. Trainees (e.g., students, residents, or fellows of any profession) may serve as participants, but not as PIs within a VA facility, and their chosen PI must be sufficiently experienced in the trainee's research interest and responsible for oversight of the trainee and the overall research project. Trainees or students must be enrolled in an institution with an educational affiliate agreement with the Atlanta VA, or appointed to a VA training program that does not need external institutional sponsorship.

All submission information and forms can be found on the Atlanta VAMC website: http://www.atlanta.va.gov/services/research/Investigators.asp
Or via the Electronic Request to Review Research Proposal system (access via the VA Intranet only): https://vaww.gateway.research.va.gov/errrp/

- 1. To begin the process of engaging in a project, you will need to set up an AREF online account. To create new account, click Create NEW Account and answer the questions and follow the workflow. This account will enable you to accomplish several things.
 - a. Register you and any staff working on projects
 - b. Complete Laboratory Annual Self Inspection Form (LASIF) if needed. (See 3.a below)
 - c. <u>Create your PAGE 18-Investigator data sheet.</u> This form is used to get the PI's information into our local research database as well as the VA national database. On an annual basis we ask PIs to update this information through their AREF account. This also requires an NIH ERA Commons ID
 - i. if you are an Emory or Morehouse faculty member, ask your department to create your Commons ID
 - ii. if you are NOT an Emory faculty member, contact Ashley Scales, PhD at Ashley.Scales@va.gov.
- 2. The Science Information Office (SIO, see contact information in 6) is your point of contact for all committee operations with the exception of the IRB. Point of contact for the Emory IRB is Daniel Roysden (droysde@emory.edu at VA 404 -321-6111 ext. 202512 or at Emory 404-712-9749). Point of Contact for all other IRBs is the HRPP Manager, Jennifer Whelan at Jennifer.Whelan@va.gov.

- 3. What subcommittee approvals do you need for your project? VA has subcommittees that report to the R&D committee. They include the Subcommittee for Research Safety (SRS), IACUC, and the IRB (Emory IRB, VA CIRB, NCI CIRB, Commercial IRB, etc). Project submissions to these subcommittees can be done all at the same time, but all relevant subcommittee approvals must be obtained before you can submit for R&D approval.
 - a. SRS (Subcommittee for Research Safety)

LASIFs are required for all research laboratories at the VA that involve biological hazards, radiation hazards, chemicals, and/or animals. New PIs have 90 days after initiating work in their laboratories to submit a new LASIF. Annually the SRS reviews completed Laboratory Annual Self-Inspection Forms (LASIFs). The SIO office will help PIs with LASIF submissions. This document applies only to:

- i. Projects being conducted at the VA.
- ii. Projects administered by AREF or VA.
- iii. If you are not sure what your project requires, you can contact the Science Information Office or the SRS Chair for clarification.
- iv. If you are using Recombinant DNA, your project will also require Institutional Biosafety Committee approval prior to commencing work. Contact the Science Information Office for more information.
- b. IACUC (Institutional Animal Care and Use Committee)- must approve all projects involving experiments with animals
 - All ACORPs must have a veterinary consultation prior to review by the IACUC. Completed ACORPs/animal protocols should be sent to: <u>George.Lathrop@va.gov</u>, (in the subject line put "VA Vet consult").
 - If animals are located at Yerkes, please send your ACORP/animal protocol to vet consult@rmy.emory.edu for consult.
 - 2. Location and funding of animal work will dictate what animal committee and form you use to obtain approval. Your submission, regardless of what form/committee, should include a memo with responses to the vet consult.
 - ii. Projects that are funded by VA or AREF must be reviewed by the VA IACUC regardless of where the studies will be performed. These projects must use the VA ACORP forms. In rare cases, the Emory animal protocol form will be accepted, but this must be discussed with the SIO and IACUC chair prior to submission.
 - iii. For VA or AREF funded projects, and if procedures are performed at Emory, submit to VA IACUC first, then to Emory IACUC. The Science Information Office will forward the approved ACORP/Vet consult to Emory for review.
 - iv. Projects funded by sources other than VA or AREF where procedures are performed at the VA must be reviewed by VA IACUC. You may use either the VA ACORP (preferred) or Emory animal protocol forms.
 - v. Projects funded by sources other than VA or AREF where procedures are performed <u>at</u> <u>Emory</u> must be reviewed by Emory IACUC.

- c. IRB (Institutional Review Board) all studies involving human subjects or the use of identified human samples or data, must be approved by an IRB (Emory IRB, NCI IRB, VA Central IRB, Commercial IRB, etc)
 - i. VA PIs obtaining approval from the Emory IRB must have an Emory sponsored account to submit to the Emory IRB. Study team members listed in the IRB submission require an Emory account (can be sponsored). If you do not have one, contact your PI or department administrator for a sponsored Emory account.
 - ii. We have an Emory IRB Liaison who is assigned to all VA projects submitting to the **Emory IRB** to help PIs through the process. The Liaison can help PIs with their IRB submission which is done through an electronic system called eIRB. If consent forms are needed, he can also make sure they meet VA requirements. Please contact Daniel Roysden at droysde@emory.edu or 404-321-6111 ext. 202512.
 - iii. Projects submitted to all IRBs except VA Central IRB require a pre-review by the PO and ISO and the IRB Liaison.

4. R&D approval-

- a. ALL relevant subcommittee approvals must be obtained before your project can be submitted for review by the R&D Committee. NO WORK CAN BE PERFORMED ON A PROJECT UNTIL NOTIFICATION TO INITIATE RESEARCH HAS BEEN PROVIDED BY THE ACOS/R.
- b. The basic R&D submission is an electronic submission to eRRRP: https://vaww.gateway.research.va.gov/errrp/. Based on the type of research you are doing, you may also be required to upload copies of any of the following forms: budget, proposal (grant, science portion), Collaborative Research Worksheet (CRW), assessment of clinical impact (signed by PI), Pharmacy Impact (signed by PI), SRS or "Biosafety" approvals, Research Data Inventory (RDI) and IRB approvals. Human subjects would include additional IRB approved forms such as informed consent, HIPAA authorization/revocation as well as others based on what is involved, i.e. drugs, devices.
- 5. Training-to perform research at the Atlanta VA, numerous training requirements must be satisfied for all research personnel (including the PI, technicians, coordinators, etc). The WOC Coordinator (WOCCoordinator@faver.foundation), 404-321-6111 ext. 206170, will help you determine what trainings are necessary. Current training requirements can be found at http://www.atlanta.va.gov/Docs/VA Training Requirements.pdf

6. **Contact Information**:

R&D Chair - Machelle Pardue, Ph.D., machelle.pardue@bme.gatech.edu

IACUC Chair – Jeffrey Boatright, Ph.D. jboatri@emory.edu

SRS/IBC Chair – William Shafer, Ph.D. Wshafer@emory.edu

Veterinarian – George Lathrop, Ph.D., George.Lathrop@va.gov

Kallie Medbery, R&D Coordinator, Mary.Medbery@va.gov, 404-321-6111 ext. 204827

Derek Key, IACUC Coordinator, derek.key@va.gov, 404-321-6111 ext. 201458

Rodney Thompson, Research Compliance Officer, <u>Rodney.Thompson8@va.gov</u>, 404-321-6111 ext. 206964 Ashley Scales, Ph.D., Administrative Officer for Research, <u>Ashley.Scales@va.gov</u>, 404-321-6111 ext. 123952 Michael Hart, MD, Associate Chief of Staff for Research, <u>Michael.hart3@va.gov</u>, 404-728-7632